

a²
3. (Amended) A pharmaceutical aerosol formulation as claimed in claim 2, wherein the fatty acid salt is selected from the group consisting of sodium, potassium and lysine salts of caprylate (C₈), caprate (C₁₀), laurate (C₁₂) and myristate (C₁₄).

a³
5. (Amended) A pharmaceutical aerosol formulation as claimed in claim 4, wherein the bile salt is selected from the group consisting of salts of cholic, glycocholic and taurocholic acids.

6. (Amended) A pharmaceutical aerosol formulation as claimed in claim 5, wherein the bile salt is selected from the group consisting of sodium and potassium salts of cholic, glycocholic and taurocholic acids.

0850105 "0303"
a⁴
9. (Amended) A pharmaceutical aerosol formulation as claimed in claim 8, wherein the surfactant is selected from the group consisting of lysophosphatidylcholines, lysophosphatidylglycerols, lysophosphatidylethanolamines, lysophosphatidylinositols and lysophosphatidylserines.

a⁵
11. (Amended) A pharmaceutical aerosol formulation as claimed in claim 10, wherein the surfactant is selected from the group consisting of diacylphosphatidylcholines, diacylphosphatidylglycerols, diacylphosphatidylethanolamines, diacylphosphatidylinositols and diacylphosphatidylserines.

12. (Amended) A pharmaceutical aerosol formulation as claimed in claim 11, wherein the surfactant is selected from the group consisting of dioctanoylphosphatidylglycerol and dioctanoylphosphatidylcholine.

13. (Amended) A pharmaceutical aerosol formulation as claimed in claim 1, wherein the surfactant is selected from the group consisting of alkyl glucosides and alkyl maltosides.

14. (Amended) A pharmaceutical aerosol formulation as claimed in claim 13, wherein the surfactant is selected from the group consisting of decyl glucoside and dodecyl maltoside.

15. (Amended) A pharmaceutical aerosol formulation as claimed in [any of] claim[s] 1[-14], wherein the propellant comprises 1,1,1,2-tetrafluoroethane (P134a), 1,1,1,2,3,3,3-heptafluoropropane (P227) or 1,1-difluoroethane (P152a).

17. (Amended) A pharmaceutical aerosol formulation as claimed in claim [15 or] 16, wherein the propellant comprises a density-matched mixture of 1,1,1,2-tetrafluoroethane (P134a) and 1,1,1,2,3,3,3-heptafluoropropane (P227).

18. (Amended) A pharmaceutical aerosol formulation as claimed in [any preceding] claim 1, wherein the medicament is a β 2-adrenoreceptor agonist, an anticholinergic bronchodilator, or a glucocorticosteroid.

19. (Amended) A pharmaceutical aerosol formulation as claimed in claim 1 [18], wherein the medicament is selected from the group consisting of salbutamol, terbutaline, rimiterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol, formoterol, clenbuterol, procaterol, broxaterol, picumeterol, TA-2005, mabuterol, ipratropium bromide, beclomethasone, fluticasone, budesonide, tipredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone, and pharmacologically acceptable esters and salts thereof.

20. (Amended) A pharmaceutical aerosol formulation as claimed in [any of] claim 1[-17], wherein the medicament is selected from the group consisting of anti-allergic medicaments; expectorants; mucolytics; antihistamines; cyclooxygenase inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists, phospholipase-A2 (PLA2) inhibitors, platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic medicaments, tranquilisers, cardiac glycosides, hormones, anti-hypertensive medicaments, antidiabetic[-] medicaments, antiparasitic[- and] medicaments, anticancer[-] medicaments, sedatives, [and] analgesic medicaments, antibiotics, antirheumatic medicaments, immunotherapies, antifungal medicaments, [and] antihypotension medicaments, vaccines, antiviral medicaments, proteins, peptides, vitamins, cell surface receptor blockers, antioxidants, free radical scavengers and organic salts of N,N'-diacetylcystine.

21. (Amended) A pharmaceutical aerosol formulation as claimed in [any preceding] claim 1, including ethanol in an amount of up to 20% by weight of propellant and surfactant.

22. (Amended) A pharmaceutical aerosol formulation as claimed in [any preceding] claim 1, including ethanol in an amount of up to 5% by weight of propellant and surfactant.

23. (Amended) A pharmaceutical aerosol formulation as claimed in [any preceding] claim 1, including another pharmaceutically active agent[s] selected from the group consisting of adjuvants, carriers, flavouring agents, buffers, antioxidants and chemical stabilisers.

24. (Amended) A pharmaceutical aerosol formulation as claimed in [any preceding] claim 1, wherein the surfactant is present in a surfactant: medicament ratio in the range of 1:50 to 1:0.2.

25. (Amended) A pharmaceutical aerosol formulation as claimed in [any preceding] claim 1, wherein at least 50% of the medicament consists of [comprises] particles having a diameter of 0.01-10 microns.

26. (Amended) A pharmaceutical aerosol formulation as claimed in claim [34] 1, wherein at least 50% of the medicament consists of [comprises] particles having a diameter of 0.1-6 microns.

27. (Amended) A pharmaceutical aerosol formulation as claimed in claim [34] 1, wherein at least 50% of the medicament consists of [comprises] particles having a diameter of 0.1-5 microns.

28. (Amended) A pharmaceutical aerosol formulation as claimed in [any of] claim[s] 25[-27], wherein at least [50%] 70% of the medicament consists of particles [within the said size range] having a diameter of 0.01-10 microns.

29. (Amended) A pharmaceutical aerosol formulation as claimed in [any of] claim[s] 25[-27], wherein at least [60%] 90% of the medicament consists of particles [within the said size range] having a diameter of 0.01-10 microns.

30. (Amended) A pharmaceutical aerosol formulation as claimed in [any of] claim[s] 25-27] 26, wherein at least 70% of the medicament consists of particles [within the said size range] having a diameter of 0.01-6 microns.

31. (Amended) A pharmaceutical aerosol formulation as claimed in [any of] claim[s 25-27] 26, wherein at least [80%] 90% of the medicament consists of particles [within the said size range] having a diameter of 0.01-6 microns.

33. (Amended) A pharmaceutical aerosol formulation as claimed in [any preceding] claim 1, wherein the concentration of medicament in the formulation is 0.1 mg/ml to 25 mg/ml [of the formulation].

34. (Amended) A method for the manufacture of a pharmaceutical aerosol formulation as claimed in [any of claims 1-33] claim 1, comprising the steps of: mixing the medicament and the surfactant [and to] in a vessel [at low temperature]; adding propellant [and optional ethanol; mixing; and adding further propellant and optional ethanol] to the vessel; and mixing the propellant with the medicament/surfactant mixture to produce a medicament/surfactant/propellant mixture.

37. (Amended) A method for the treatment of a patient in need of therapy with a medicament, comprising administering to said patient a therapeutically effective amount of [the] a pharmaceutical aerosol formulation [as claimed in any of claims 1-33] comprising a HFA propellant; a physiologically effective amount of the medicament; and a surfactant selected from the group consisting of a C₈-C₁₆ fatty acid or salt thereof, a bile salt, a phospholipid, and an alkyl saccharide.

Add new claims 38-45.

--38. The method of claim 37, wherein said propellant comprises 1,1,1,2-tetrafluoroethane (P134a), 1,1,1,2,3,3,3-heptafluoropropane (P227) or 1,1-difluoroethane (P152a).--

--39. The method of claim 37, wherein said surfactant is selected from the group consisting of sodium, potassium and lysine salts of caprylate (C₈), caprate (C₁₀), laurate (C₁₂) and myristate (C₁₄).--

--40. The method of claim 37, wherein said surfactant is a trihydroxy bile salt.--

--41. The method of claim 37, wherein the surfactant is selected from the group consisting of lysophosphatidylcholines, lysophosphatidylglycerols, lysophosphatidylethanolamines, lysophosphatidylinositols, lysophosphatidylserines, diacylphosphatidylcholines, diacylphosphatidylglycerols, diacylphosphatidylethanolamines, diacylphosphatidylinositols, and diacylphosphatidylserines.--

--42. The method of claim 37, wherein the surfactant is an alkyl glucoside or an alkyl maltoside.--

--43. The method of claim 37, wherein the medicament is a β 2-adrenoreceptor agonist, an anticholinergic bronchodilator, or a glucocorticosteroid.--

At 6
ended
45T00-030199

--44. The method of claim 37, wherein the medicament is selected from the group consisting of anti-allergic medicaments; expectorants; mucolytics; antihistamines; cyclooxygenase inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists, phospholipase-A2 (PLA2) inhibitors, platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic medicaments, tranquilisers, cardiac glycosides, hormones, anti-hypertensive medicaments, antidiabetic medicaments, antiparasitic medicaments, anticancer medicaments, sedatives, analgesic medicaments, antibiotics, antirheumatic medicaments, immunotherapies, antifungal medicaments, antihypotension medicaments, vaccines, antiviral medicaments, proteins, peptides, vitamins, cell surface receptor blockers, antioxidants, free radical scavengers, and organic salts of N,N'-diacetylcystine.--

--45. The method of claim 34, further comprising the step of mixing additional propellant with the medicament/surfactant/propellant mixture.--